

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK) <i>REDACTED VERSION</i>

**PLAINTIFFS' BRIEF IN SUPPORT OF *DAUBERT*
MOTION TO PRECLUDE DEFENSE EXPERT WILLIAM J. LAMBERT, PH.D.,
FROM OFFERING CLASS CERTIFICATION OPINIONS**

HONIK LLC
1515 Market St., Suite 1100
Philadelphia, PA 19102

KANNER & WHITELEY, LLC
701 Camp St.
New Orleans, LA 70130

GOLDENBERG LAW, PLLC
800 LaSalle Ave., Suite 2150
Minneapolis, MN 55402

On the Brief:
Ruben Honik, Esq.
David J. Stanoch, Esq.
Marlene Goldenberg, Esq.

TABLE OF CONTENTS

TABLE OF AUTHORITIES ii

I. INTRODUCTION 1

II. LEGAL STANDARD..... 2

 A. Rule 26 and the Contents of the Expert Report 2

 B. *Daubert* Standard 2

III. ARGUMENT 4

 A. William Lambert Should Be Precluded From Opining That [REDACTED]
 [REDACTED] 4

 B. Dr. Lambert Should Be Precluded from Testifying That [REDACTED]
 [REDACTED] 8

IV. CONCLUSION..... 12

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>ABB Air Preheater, Inc. v. Regenerative Env't Equip. Co.</i> , 167 F.R.D. 668 (D.N.J. 1996).....	2
<i>Advo, Inc. v. Philadelphia Newspapers, Inc.</i> , 51 F.3d 1191 (3d Cir. 1995).....	11
<i>Apotex, Inc. v. Cephalon, Inc.</i> , 321 F.R.D. 220 (E.D. Pa. 2017).....	8
<i>Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.</i> , 509 U.S. 209, 113 S. Ct. 2578, 125 L. Ed. 2d 168 (1993).....	8
<i>Claar v. Burlington, N.R.R.</i> , 29 F.3d 499 (9th Cir. 1994)	3
<i>Daubert v. Merrell Dow Pharmaceuticals, Inc.</i> , 43 F.3d 1311 (9th Cir. 1995)	3
<i>Daubert v. Merrell Dow Pharmaceuticals, Inc.</i> , 509 U.S. 579 (1993).....	3
<i>Doherty v. Allstate Indem. Co.</i> , 734 F. App'x 817 (3d Cir. 2018)	11
<i>Elcock v. Kmart Corp.</i> , 233 F.3d 734 (3d Cir. 2000).....	3
<i>General Elec. Co. v. Joiner</i> , 522 U.S. 136, 118 S. Ct. 512, 139 L.Ed.2d 508 (1997).....	3
<i>Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.</i> , 289 F. Supp. 2d 493 (D. Del. 2003).....	7
<i>In re Paoli R.R. Yard PCB Litigation</i> , 35 F.3d 717 (3d Cir. 1994).....	3
<i>Kumho Tire Co. v. Carmichael</i> , 526 U.S. 137 (1999).....	3
<i>Lipton v. Mountain Creek Resort, Inc.</i> , No. CV134866KMMAH, 2019 WL 4597205 (D.N.J. Sept. 23, 2019).....	2

Magistrini v. One Hour Martinizing Dry Cleaning,
180 F. Supp. 2d 584 (D.N.J. 2002) 3, 4

Meadows v. Anchor Longwall & Rebuild, Inc.,
306 F. App'x 781 (3d Cir. 2009) 8

Meyers v. Nat'l R.R. Pass. Corp. (Amtrak),
619 F.3d 729 (7th Cir. 2010) 2

Mondis Tech. Ltd. v. LG Elecs., Inc.,
No. 15-4431, 2021 WL 4077563 (D.N.J. Sept. 8, 2021) 8

Padillas v. Stork-Gamco, Inc.,
186 F.3d 412 (3d Cir. 1999)..... 3

Rhoads Indus., Inc. v. Shoreline Foundation, Inc.,
No. 15-921, 2021 WL 2778562 (E.D. Pa. July 2, 2021) 7

United States ex rel. Penelow v. Janssen Prod., LP,
No. CV127758ZNQLHG, 2022 WL 94535 (D.N.J. Jan. 10, 2022) 8

Statutes

21 U.S.C. § 331(a) 9

21 U.S.C. § 351(a)(1)..... 9

Rules

Fed. R. Civ. P. 26(a)(2)..... 2

Rule 26(a)(2)(B)..... 2

Fed. R. Evid. 702 2

Fed. R. Evid. 702(b)..... 8

I. INTRODUCTION

Plaintiffs submit this *Daubert* motion against Aurobindo's¹ expert Dr. William Lambert with regard to his opinions (i) on [REDACTED] [REDACTED]; and (ii) on [REDACTED]. Dr. Lambert's opinions are unreliable, unreliably applied, and are unhelpful because he admits his opinions do not rest on sufficient facts or data.

First, despite being purportedly offered to opine on [REDACTED] [REDACTED], Dr. Lambert actually *has no opinions on the matter at all*.² He never opines that [REDACTED], let alone identifies any method he followed to reach such a conclusion or the facts on which he might base it. Rather, Dr. Lambert simply disagrees with Plaintiffs' cGMP expert, Mr. John Quick. An expert whose written report does not contain a particular affirmative opinion, and who later confirms that he does not offer that particular affirmative opinion (but at best may disagree with a competing expert), cannot be permitted to testify otherwise.

Second, Dr. Lambert's speculation about [REDACTED] must be excluded as contrary to the record facts in this case. As an initial matter, Dr. Lambert was equivocal on whether he was even offering such an opinion in this case, which would be outside his areas of expertise. Nonetheless, the facts in this case—established by Aurobindo's own corporate witnesses and admitted by Dr. Lambert at deposition—contradict the notion that [REDACTED]. Thus, even assuming Dr. Lambert meant to offer a

¹ Dr. Lambert testified at his deposition that the opinions he offers were [REDACTED] [REDACTED]. Ex. 2 (Lambert Tr.) at 20:15-21:4; 28:21-29:9.

² Ex. 2 (Lambert Tr.) at 35:8-13.

██████ opinion, it would be speculative and unhelpful due to a complete lack of any factual support.

For these reasons, expressed more fully below, Dr. Lambert's opinions as identified herein should be excluded.

II. LEGAL STANDARD

A. Rule 26 and the Contents of the Expert Report

Federal Rule of Civil Procedure 26(a)(2) governs the disclosure of expert testimony and specifically the contents of an expert report. Relevant to this Motion, the Rule states the following: "The report must contain: (i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them" Fed. R. Civ. P. 26(a)(2)(B)(i) & (ii). A failure to submit an expert report that complies with Rule 26 is an independent basis for the exclusion of the expert's testimony. *See, e.g., Meyers v. Nat'l R.R. Pass. Corp. (Amtrak)*, 619 F.3d 729, 734 (7th Cir. 2010) ("The consequence of non-compliance with Rule 26(a)(2)(B) is exclusion of an expert's testimony[.]" (internal quotations and citations omitted)).

Experts are therefore only permitted to testify at trial in accordance with the contents of their reports. *See* Fed. R. Civ. P. 26(a)(2)(B)(i); *see also Lipton v. Mountain Creek Resort, Inc.*, No. CV134866KMMAH, 2019 WL 4597205, at *7 (D.N.J. Sept. 23, 2019) ("[T]he court generally will not permit an expert to testify beyond the scope of his or her report."). "Compliance with Rule 26(a)(2) is thus a condition precedent to the use of expert testimony at trial." *ABB Air Preheater, Inc. v. Regenerative Env't Equip. Co.*, 167 F.R.D. 668, 671 (D.N.J. 1996).

B. Daubert Standard

The admissibility of expert testimony is determined pursuant to Federal Rule of Evidence

702. The party offering the proposed expert testimony bears the burden of establishing the admissibility of the testimony by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 417-18 (3d Cir. 1999). An “expert’s opinions must be based on the methods and procedures of science, rather than on subjective belief or unsupported speculation.” *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 742 (3d Cir. 1994) (citations and internal quotations omitted). Thus, “the expert must have ‘good grounds’ for his or her belief.” *Id.* (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993)). These good grounds must support each step of the analysis and, “any step that renders the analysis unreliable under the *Daubert* factors renders the expert’s testimony inadmissible.” *Id.* at 745. Judges within this Circuit also consider how and when the methodology is used outside of litigation. *Paoli*, 35 F.3d at 742 (discussing reliability factors under *Daubert* and Third Circuit case law).

Furthermore, “*Daubert*’s gatekeeping requirement make[s] certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Elcock v. Kmart Corp.*, 233 F.3d 734, 746 (3d Cir. 2000) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)); *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594 (D.N.J. 2002), *aff’d*, 68 Fed. Appx. 356 (3d Cir. 2003). In addition, the following factors are relevant when determining reliability:

(i) whether the expert’s proposed testimony grows naturally and directly out of research the expert has conducted independent of the litigation (*see Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995)); (ii) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion (*see General Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 139 L.Ed.2d 508 (1997)); (iii) whether the expert has adequately accounted for alternative explanations (*see Claar v. Burlington, N.R.R.*, 29 F.3d 499 (9th Cir. 1994)).

Magistrini, 180 F. Supp. 2d at 594–95.

III. ARGUMENT

A. William Lambert Should Be Precluded From Opining That [REDACTED]

Dr. Lambert presents an overview of [REDACTED] in his report.³ Yet, he does not offer an affirmative opinion that [REDACTED]. Dr. Lambert confirmed at deposition that he does not offer any affirmative opinions in this regard. He was asked multiple times where in his report he gave the opinion that [REDACTED]. Yet each time this question was posed, Dr. Lambert was unable to cite to a single paragraph where he offered the opinion that [REDACTED]

Ex. 2 (Lambert Tr.) at 35:9-23.⁴

But [REDACTED]

[REDACTED].⁵ Dr. Lambert was then given another chance to identify the location in his report of [REDACTED]:

³ See, e.g., Ex. 1 (Lambert Rpt.) at ¶¶ 26-29 (section entitled [REDACTED]).

⁴ The FDA found that Aurobindo violated cGMPs, so this [REDACTED]

⁵ Ex. 1 at ¶ 29.

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

Ex. 2 at 40:16-41:4, 41:20-43:5.

After citing to paragraph [REDACTED] of his report and quickly realizing that it did not provide the sought after opinion, Dr. Lambert continued to try to engraft an [REDACTED] opinion onto his report that does not appear anywhere in it:

[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Ex. 2 at 43:14-44:9.

Rather than identify in his report an affirmative opinion about [REDACTED]

[REDACTED] Dr. Lambert merely said he disagreed with Plaintiffs' expert, Mr. John Quick:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Ex. 2 at 47:4-13. Of course, mere disagreement without explanation is no more than a net opinion, if it is an opinion at all. When pressed to identify the location of any affirmative opinions on [REDACTED], Dr. Lambert could not do so:

[REDACTED]

[REDACTED]

Ex. 2 at 47:14-48:5. Again, semantic somersaults do not constitute analysis and opinion.

In addition to being unable to point to a single place in his report where he explicitly gives the opinion that [REDACTED] (let alone where he sets forth either a methodology he followed to reach this opinion, or the facts he applied pursuant to that

methodology), Dr. Lambert conceded that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Ex. 2 at 75:8-13.⁶

An expert cannot testify to an opinion outside the scope of his expert report. *See supra* Part II.A. An expert that confines his opinions in one way cannot then testify beyond those opinions. *See, e.g., Rhoads Indus., Inc. v. Shoreline Foundation, Inc.*, No. 15-921, 2021 WL 2778562, at *14 (E.D. Pa. July 2, 2021); *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 289 F. Supp. 2d 493, 500 (D. Del. 2003). Here, Dr. Lambert does not offer anywhere in his report the affirmative opinion that [REDACTED].

When asked, he could not point to any such opinion in his report. Therefore, because Dr. Lambert does not offer an affirmative opinion anywhere in his report that [REDACTED]—let alone explain any method he might follow to reach such a [REDACTED]

[REDACTED]

[REDACTED]. As this Court previously ruled in this litigation as to another defense expert, Dr. Lambert's simply stating that he disagrees with Plaintiffs' expert, Mr. Quick, is not enough.⁷

⁶ *See also, e.g.,* Ex. 2 at 59:11-21 [REDACTED]

[REDACTED]

⁷ Ex. 3 (Mar. 2, 2022 Hr'g Tr.) at 162:6-8 [REDACTED]

[REDACTED]

B. Dr. Lambert Should Be Precluded from Testifying That [REDACTED]

Dr. Lambert should be precluded from testifying that [REDACTED] because his opinions are not rooted in sufficient facts or data and are therefore unreliable. *See* Fed. R. Evid. 702(b); *United States ex rel. Penelow v. Janssen Prod., LP*, No. CV127758ZNQLHG, 2022 WL 94535, at *3 (D.N.J. Jan. 10, 2022) (“The purported expert’s testimony “must be based on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation.’”). Expert testimony that is contrary to law or fact, or that seeks to misstate the applicable law to the jury, is unhelpful. *See, e.g., SEC v. Ambassador Advisors, LLC*, -- F. Supp. 3d –, *5 (E.D. Pa. Dec. 21, 2021). Expert analysis also must have sufficient support in facts or data for the conclusions reached. *See, e.g., Mondis Tech. Ltd. v. LG Elecs., Inc.*, No. 15-4431, 2021 WL 4077563, at *3 (D.N.J. Sept. 8, 2021). An expert’s opinion is inadmissible if it “is both contrary to the record...[and] is contrary to the law.” *See, e.g., Apotex, Inc. v. Cephalon, Inc.*, 321 F.R.D. 220, 236 (E.D. Pa. 2017). Opinions that rest on “assumptions and conclusions that are not supported by the factual record” have been excluded on the basis that they would not “aid the jury in resolving a factual dispute” because they do not “fit under the facts of the case.” *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 F. App’x 781, 790 (3d Cir. 2009) (internal citations and quotations omitted).⁸

⁸ “When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury’s verdict.” *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242, 113 S. Ct. 2578, 2598, 125 L. Ed. 2d 168 (1993) (disregarding unsupported facts put forth by expert at summary judgment stage).

In his deposition, Dr. Lambert did not seem confident that he had even offered an opinion on [REDACTED]. *See, e.g.*, Ex. 2 at 106:3-5 [REDACTED] [REDACTED].⁹ This is unsurprising, given that Dr. Lambert is neither an economist (and thus not qualified to opine on economic damages modeling) nor a medical doctor. When Dr. Lambert was asked again if he planned to testify that [REDACTED] [REDACTED], he equivocatingly stated that he instead planned to testify that [REDACTED] [REDACTED],¹⁰ although he does not quantify or posit [REDACTED] might have had or explain how or why he gets to that rumination.

While Dr. Lambert's [REDACTED] opinion was not expressed strongly to begin with (assuming, *arguendo*, he properly expressed it at all), there is simply no evidentiary or legal support for it anywhere. Instead, the undisputed evidence—which Dr. Lambert ignored in preparing his report, but which he admitted to at deposition—shows that [REDACTED].

The law governing pharmaceutical drugs is clear: a drug is deemed adulterated when it is contaminated or when it is made in a facility that fails to comply with cGMPs. *See, e.g.*, 21 U.S.C. § 351(a)(1). It is further illegal to introduce any adulterated drug into commerce in the United States. *See* 21 U.S.C. § 331(a). [REDACTED] [REDACTED].¹¹ For this reason alone, Dr. Lambert's tentative opinion that [REDACTED] is inadmissible.

⁹ *See also id.* at 106:7-12 [REDACTED]
[REDACTED].

¹⁰ Ex. 2 at 106:16-18 (emphasis added).

¹¹ *See id.* [REDACTED]
[REDACTED]

Were that not enough, Aurobindo's own Rule 30(b)(6) designee on regulatory issues and Director of Regulatory Affairs, Ms. Blessy Johns, testified that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].¹² Ms. Johns also testified that [REDACTED]

[REDACTED].¹³

Aurobindo's Chief Quality Officer, Dr. Ambati Rama Mohana Rao, similarly agreed that

[REDACTED]:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

¹² Ex. 4 (Johns Tr.) at 98:17 – 99:10.

¹³ Ex. 4 at 40:21 – 41:18.

Ex. 5 at 235:5-235:18, 235:23-236:4. Dr. Lambert's uncertain opinion about some non-zero [REDACTED] is directly at odds with the sworn testimony of Aurobindo's own witnesses.

Further, in purportedly [REDACTED], Dr. Lambert testified that he was unaware that [REDACTED].¹⁴ Dr. Lambert also conceded that if given the choice [REDACTED].¹⁵ Moreover, Dr. Lambert, who is not an economist or doctor, [REDACTED], let alone adequately explain and apply a reliable method to do so.¹⁶

In sum, Dr. Lambert's speculative opinion that [REDACTED] (an opinion that he is not even confident he offers) is wholly unsupported by the factual record. Because Dr. Lambert failed to consider the relevant law, failed to rely upon facts to rebut the admissions of Aurobindo's own witnesses (or to consider the testimony of Aurobindo's own witnesses), and was not even sure he was offering a "value" opinion in the first place, Dr. Lambert should not be permitted to offer these unreliable opinions at trial. *See, e.g., Doherty v. Allstate Indem. Co.*, 734 F. App'x 817, 823 (3d Cir. 2018) (affirming summary judgment and exclusion of expert testimony where the "record is clear" that expert testimony was inconsistent with the factual record); *Advo, Inc. v. Philadelphia Newspapers, Inc.*, 51 F.3d 1191, 1198 (3d Cir. 1995) (same).

¹⁴ Ex. 2 at 255:4-20.

¹⁵ Ex. 2 at 256:10-19.

¹⁶ *See, e.g.,* Ex. 2 at 234:5 – 236:5.

IV. CONCLUSION

For the foregoing reasons, Dr. Lambert should be precluded from offering any opinions related to [REDACTED].

Respectfully,

PLAINTIFFS' CO-LEAD COUNSEL

By: /s/Ruben Honik
Ruben Honik
HONIK LLC
1515 Market St., Suite 1100
Philadelphia, PA 19102
267-435-1300 (t)
267-263-7497 (f)
ruben@honiklaw.com

Dated: May 3, 2022

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 3, 2022, a true and correct redacted copy of the foregoing was filed and served via the court's CM/ECF system, and an unredacted version was served on the court and the Defense Executive Committee via email.

/s/ David J. Stanoch

David J. Stanoch